Remarks

This application is a divisional application based on Serial No. 09/397,392, filed September 16, 1999. When the current application was filed, applicants amended the specification to contain a specific reference to the parent application. Since that time, the parent application has issued as a patent. Accordingly, applicants have amended the specific reference to include the patent number of the parent application, U.S. Patent No. 6,423,051.

In the Office Action of July 9, 2003, the Examiner made the following rejections to claims 16-21: (1) Claim 21 was rejected under Section 112, second paragraph, for reciting the limitation, "as in claim 1"; (2) Claim 16 was rejected under Section 102 for anticipation by Amplatz, U.S. Patent No. 4,995,866; and (3) Claims 17-21 were rejected under Section 103 for obviousness over the combination of Amplatz and Gifford, U.S. 5,695,504. Applicants respectfully request that the application be reconsidered and allowed for the reasons explained below.

Claim 21 Should Not Be Rejected under Section 112.

First as to the Section 112 rejection of claim 21, applicants respectfully submit that this rejection has already been addressed in the preliminary amendment. Claim 21 originally contained a reference to cancelled claim 1 but this reference was deleted in a preliminary amendment which was filed with the U.S. Patent Office

on January 24, 2002, and substitute language was added to claim 21. Accordingly, the Section 112 rejection has already been addressed and should be withdrawn.

Brief Description of Claim 16 Changes

In response to Examiner's rejection and in light of the newly cited prior art, applicant has amended independent claim 16. Amended claim 16 is now directed to a system for accessing an anatomic space having a wall with an outer surface which comprises an access tube and a needle. The access tube has a distal end which can be selectively embedded into tissue. More specifically, the access tube is adapted for engagement with the outer surface such that the proximal movement of the distal end causes corresponding enlargement of the anatomic space. The needle has a lumen therethrough and is configured to pass through the access tube and penetrate into the anatomic space when the access tube is embedded into the anatomic space wall. Dependent Claims 17-20 depend directly or indirectly from amended Claim 16, and therefore also include these features.

Claim 16 Is Not Anticipated and Would Not be Obvious in View of the Prior Art.

Claim 16 was rejected solely based on the Amplatz patent. However, it is respectfully submitted that Amplatz does not teach or suggest the invention, as recited in amended claim 16.

Figures 6A-6D of Amplatz' disclosure (which are designated as "Prior Art" by Amplatz) are relied upon by the Examiner and illustrate a combined needle and dilator apparatus being inserted into a blood vessel for the introduction of a catheter. In Figures 6A-6D, the "prior art" apparatus is shown and described as including a needle 60 which has a cutting edge 61 and a sheath 62 which is carried about the needle 60 in a position which is proximately located to the cutting edge 61. The "prior art" needle and sheath are advanced into the lumen of the blood vessel 50.

In contrast to amended claim 16, the "prior art" sheath 62 does not engage an outer surface to provide enlargement of the anatomic space upon proximal movement. Figures 6B-6D illustrate that the forwardly facing shoulder 63 of the sheath 62 passes <u>through</u> the outer wall of the blood vessel 50 into the lumen defined by the blood vessel. Amplatz discloses that the sheath 62 must <u>not</u> be embedded for engagement with the outer surface of the wall to provide for enlargement of the blood vessel 50. Instead, the sheath 62 must be inserted into the blood vessel 50 for engagement with the inner surface of the blood vessel 50 so as to dilate the blood vessel.

Similarly, the additional disclosure in Amplatz does not teach the subject matter of claim 16. Amplatz' apparatus includes a needle 10 and a dilating sheath 20. The only difference between Amplatz' apparatus and the disclosed "prior art" apparatus in

Figures 6A-6D is that the head 12 of Amplatz' needle 10 and the front portion 21 of the sheath 20 have substantially the same external diameter. Having the same external diameter ensures that the front portion 21 of the sheath 20 does not contact the outer surface of the blood vessel wall during insertion of the sheath 20 and needle 10 into the blood vessel 50. The importance of having the front portion 21 of the sheath 20 slide smoothly and readily through the outer wall of the blood vessel 50 without engaging the outer surface is described at column 5, lines 56-64 of Amplatz. Therefore, Amplatz' sheath 20 clearly does not engage the outer surface to provide enlargement of the anatomic space upon proximal movement, as required by amended claim 16.

It is further respectfully submitted that Amplatz' disclosure would not render the claimed system obvious. Indeed, the "prior art" apparatus of Figures 6A-6D expressly teaches away from a sheath which engages the outer surface for enlargement of the anatomic space upon proximal movement. At column 5, lines 13-15, Amplatz acknowledges that any contact by the shoulder 63 of the sheath 62 against the outer surface of the blood vessel 50 causes the blood vessel 50 to collapse locally, which is the opposite of the intended structure and function of the invention set forth in claim 16.

Amplatz' own alleged invention (see Figures 7A-7C) further teaches away from amended claim 16. Amplatz allegedly overcomes

the drawbacks in the prior art by sizing the needle 10 and sheath 20 to present a substantially smooth cylindrical surface so that the front portion 21 of the sheath does not engage the outer surface of the blood vessel 50. In this way, Amplatz' sheath 20 specifically teaches avoidance of any significant engagement with the outer surface. More particularly, Amplatz teaches away from the subject matter of claim 16 which intentionally engages the outer surface to provide for enlargement of the anatomic space upon proximal movement of the access tube. For these reasons, applicants respectfully submit that amended claim 16 would not be obvious.

Claims 17-20 depend on newly amended Claim 16. Dependent claims 17-20 would not be obvious, as they contain all the features of claim 16 which should be allowable for the reasons stated above. Moreover, claims 17-20 would not be obvious over the alleged combination of Amplatz and Gifford. Gifford also does not teach or suggest a structure which engages an outer surface for enlarging an anatomic space upon proximal movement. Rather, Gifford discloses various vascular anastomosis devices which attach bypass grafts to a blocked blood vessel for the purpose of reestablishing blood flow to essential tissue areas which have been compromised by harmful conditions such as occlusions or stenosis. Gifford's device is clearly different from the intended structure and function of

claims 17-20 as well as independent claim 16. Claims 17-20 thus would not be obvious over the alleged combination.

Claim 21 Is Not Anticipated and Would Not be Obvious in View of the Prior Art.

Claim 21 was rejected based on the combination of the Amplatz patent with the Gifford patent. Briefly, claim 21 discloses a kit for accessing the pericardial space between the visceral and parietal pericardium. The kit comprises an access tube having a distal end which can be selectively embedded into tissue, and instructions for use which set forth a method for accessing an anatomic space having a wall with an outer surface. The method comprises the steps of embedding a distal end of an access tube into the outer surface, and drawing the access tube proximally to raise the wall over the anatomic space and to enlarge the anatomic space. The method further comprises the step of introducing an access device through the access tube, penetrating the wall and into the anatomic space while the access tube stabilizes the wall.

In the Office Action, the examiner rejected the subject matter of claim 21 based, in part, on Gifford's two-piece anastomosis device 496, as shown in Figures 40A-40D. The anastomosis device 496 has two concentric cylindrical flange rings 497, 498. Each flange ring 497, 498 includes corresponding locking features 501, 502 which project at a downward angle and are disposed in either a clockwise or counterclockwise direction.

In the Office Action, it is presumed that it would be obvious to combine the flange rings 497, 498 of Gifford's anastomosis device with the shoulder 63 of the sheath 62 in Amplatz in order to engage the outer wall of tissue. However, such a combination is counterintuitive to the express teachings of these references.

First, this combination is contrary to the express teaching of Amplatz. As evidenced from Amplatz' teachings, the front portion 21 or shoulder 63 of the sheath must not contact the outer wall of the blood vessel. Amplatz' own apparatus is specifically designed to avoid such contact and achieve a completely smooth entry into the blood vessel. Thus, as discussed above, Amplatz expressly teaches away from any significant contact of the outer surface of the blood vessel including the type of engagement shown and described in Gifford.

Second, Gifford also teaches away from any combination with the dilator apparatus in Amplatz. An essential requirement of Gifford's anastomosis device is that it provide a relatively permanent, completely leak-free seal between blood flow paths (Column 1, lines 56-62). The blood must not leak from the seal between the flow paths. Otherwise, the graft must be resutured to close such leaks. Clearly, the structural and functional requirements of Gifford are contrary to those of Amplatz.

The sheath in Amplatz is not designed to provide a leak-free seal between the apparatus and the blood vessel. Rather, Amplatz'

sheath obtains temporary access to the blood vessel for dilation of the blood vessel so as to allow introduction of a catheter for performing a medical procedure. Once the catheter is inserted, the sheath can be removed. The sheath is not intended to establish a leak-free seal with the blood vessel. Indeed, the distal end of the sheath cannot be sealed to the blood vessel because it must be advanced along the lumen of the blood vessel to effect dilation. For these reasons, it is respectfully submitted that Amplatz and Gifford are not properly combinable and, thus, claims 17-21 would not be obvious.

Conclusion

It is respectfully submitted that claims 16-21 clearly distinguish from the prior art references cited by the Examiner. Reconsideration and allowance of these claims are respectfully requested.

Respectfully submitted,

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